



TECHNICAL FILE

PRODUCT NAME:

Family- Natural Rubber Latex (NRL) Condom with Flavoured Silicone Lubricant

REF:

MDTF 113

REASON FOR ISSUE:

Refer to cover page

PROJECT NUMBER:

N/A

ISSUE NUMBER:

14

DATE:

May 2021

4. EC Declaration of Conformity

Product Information

Product name: Natural rubber latex condom with flavoured silicone lubricant
 Brand: Durex
 Reference: MDTF 113
 Issue Number: 14
 Component Number: *3085107, 3085111, GPA5000032, GPA5000028
 CS000175, CS000176, CS000344, CS000349, CS000350, CS000539
 **8296761, 8296762, 8296763, 8296765

Manufacturer

Name: Reckitt Benckiser (UK) Ltd
 Address: Dansom Lane, Hull, East Yorkshire, HU8 7DS
 Country: UK

Authorized Representative/Distributor in Europe

Name: RB NL Brands B.V
 Address: Schiphol Boulevard 207, 1118 BH Schiphol.
 Country: Netherlands

Registration Information

Notified Body ID: 1639
 Name: SGS Belgium NV
 Address: Noorderlaan 87, BE-2030 Antwerpen.
 Country: Belgium
 CE Certificate No.: GB19/963047
 Date CE marked: 10th September 2020

Originally CE Marked *19th March 2010 and **8th June 2018 under SGS UK, 0120. CE Certificate No GB99/50557.01.

Conformity Assessment

Classification: Medical Device Class IIb Rule: 14
 Route to compliance: Annex II (excluding Section 4.0) of MDD 93/42/EEC Council Directive
 Standard Applied: See Appendix 1

Reckitt Benckiser Healthcare (UK) declares that the above-mentioned product is in conformity with essential requirements and provisions of Council Directive 93/42/EEC and conforms to the standards listed in Appendix 1.

Signatures

Name and function:
 Mark Ainsworth
 Senior Global Regulatory Manager

Signature:

DocuSigned by:

Mark Ainsworth

Date: 25-May-2021 | 18:05 BST



Signer Name: Mark Ainsworth
 Signing Reason: I approve this document
 Signing Time: 25-May-2021 | 18:02 BST

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